A Dissertation On

"ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY"

Submitted By

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I certify that the dissertation entitled "**ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY**" is the record of original research work carried out by Dr. VIJAYAKUMAR MONICA, in the Department of Acupuncture & Energy Medicine, Government Yoga & Naturopathy Medical College & Hospital, Chennai – 600 106 submitted for the degree of DOCTOR OF MEDICINE (M.D) in Acupuncture & Energy Medicine under my guidance and supervision, and that this work has not formed the basis for the award of any degree, associateship, fellowship or other titles in this University or any other University or Institution of higher learning

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I, Dr. VIJAYAKUMAR MONICA solemnly declare that dissertation titled "ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY" is a bonafide and genuine research work carried out by me at Government Yoga & Naturopathy Medical College & Hospital, Chennai from May 2017 – May 2017 under the guidance and supervision of Dr. R. S. HIMESWARI, Head of the Department, Department of Acupuncture and Energy Medicine, Govt. Yoga & Naturopathy Medical College & Hospital, Chennai. This dissertation is submitted to The Tamilnadu Dr. M.G.R. Medical University towards partial fulfillment of requirement for the award of M.D. Degree (Branch – III) in Acupuncture & Energy Medicine.

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The Institution Ethical Committee of Government Yoga & Naturopathy Medical College & Hospital, Chennai reviewed and discussed the application for approval of "ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS - A COMPARITIVE STUDY" for project work submtted by Dr. Vijayakumar Monica, 2nd Year M.D. Acupuncture & Energy Medicine, Post Graduate, Government Yoga & Naturopathy Medical College & Hospital, Chennai – 600 106.

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LIST OF ABBREVATIONS

PARTICULAR	ABBREVIATION
Pre-exam anxiety	PEA
Five element acupuncture	FEA
World health organization	WHO
Complementary and alternative medicine	CAM
National institutes of health	NIH
Western acupuncture	WA
Bachelor of naturopathy and yogic sciences	BNYS
Visual analog scale for anxiety	VAS-A
Complementary and alternative medicine	CAM
State trait anxiety inventory	STAI
State trait anxiety inventory – form y	STAI-Y6
Beck depression inventory	BDI
Diagnostic and statistical manual of mental disorders- IV	DSM-IV
Anxiety achievement test	AAT
Test anxiety questionnaire	TAQ
Test anxiety	TA
Hypothalamo–pituitary–adrenal axis	HPA AXIS
Gamma-aminobutyric acid	GABA

International Classification of Diseases	ICD
Anxiety disorders	AD
Generalized anxiety disorder	GAD
Social anxiety disorder	SAD
Post-traumatic stress disorder	PTSD
Obsessive compulsive disorder	OCD
Children's Test Anxiety Questionnaire	CTAQ
Test Anxiety Inventory for Children and Adolescent	TAICA
Irwin. G. Sarason Reactions to Tests Scale	RTT
Test Anxiety Scale	TAS
Suinn Test Anxiety Behavior Scale	STABS
Worry-Emotionality Questionnaire	W-E Q
Inventory of Test Anxiety	ITA
Central nervous system	CNS
State Test Anxiety Scale	STAS
Taylor Manifest Anxiety Scale	TMAS
Adult Manifest Anxiety Scale	AMAS

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INTRODUCTION

1. INTRODUCTION

Anxiety is a state of emotion often characterized by a not so pleasant state of internal turmoil[1,2], often associated with nervous behavior, such as pacing back and forth, physical issues, and rumination[3,4,5]. Further, it has also shown to impair memory, concentration, decision making, learning and is associated with lower academic performance.[6,7] Anxiety is a word derived from Latin roots 'anxius' which means a state of depression and agitation with feeling of distress in the precordial region.[8]

Pre-exam anxiety is a combination of fear of failure, dread, worry and catastrophizing along with physiological over-arousal, stress and physical symptoms that occur before or during exam/test situations.[9,10] Pre-exam anxiety creates barriers in concentration to learn and perform.[11] Test anxiety can distress anyone, a primary or high school student, an undergraduate or post-graduate student, or a worker who has to take tests for career development or qualification.

Pre-exam stress is usually predominant in medical students and students appearing for competitive examinations. Several studies have recorded the prevalence of stress among medical students ranging from 27% to 73%.[12] As freshmen, Medical student's first year exam is probably the most stressful experience. The gradation from school to professional medical college can be identified as critical stage among the students. Additionally excessive study load, new medical terminologies, clinical environment, peer pressure, sleep deprivation, inadequate support adds to the mental attribute of medical

students. Pre-exam anxiety in medical students can also be associated with changes in the physical and mental health such as increased anxiety, increased negative mentality that influences the performance of students.

Four major sectors of reported stresses which can contribute to pre-exam anxiety are improper lifestyle, lack of needed information, style of studying and psychological aspects.[13] Improper lifestyle includes lack of sufficient physical activity, lack of adequate rest, improper nutrition and defective of time management skills which contributes to pre-exam anxiety as reported by many authors.[14,15]

Psychological aspects contributing significantly to pre-exam anxiety are irrational and negative thinking about examination, its outcomes and feeling of lack of control over examination situation (e.g. Experiencing to be blank during examination) are reported by many authors.[16, 17] Another reported cause for pre-exam anxiety in medical students is their perception of excess course load.[18] Examination system[19] is itself is an important stress factor for students. Authors report that parental pressure is also related with high levels of worry, irrelevant thoughts regarding exam, and physical symptoms associated with anxiety prior to and during the examination.[20]

Other reasons for pre-exam anxiety may include procrastination, and poor performance in the previous examination.[21] Characteristics of examination environment like: nature of the task, atmosphere, level of difficulty, availability of time, examiner's

nature, mode of effectuation and physical settings may affect the level of anxiety experienced by the student.[22, 20]

Pre-exam anxiety is known to initiate into a vicious cycle. After experiencing pre-exam anxiety in one test, the student may become frightened of it happening again and he/she becomes more anxious and worried than the previously experienced anxiety. If the cycle continues unattended or unacknowledged, or the student seeking help, the student may begin to feel helpless and worse in every examination situation.[23] Students who experience pre-exam anxiety often have siblings or parents who have similar exam anxiety or other types of anxiety moreover anxiety disorder seems to have certain genetic components.[24]

Symptoms of pre-exam anxiety can range between moderate to severe. Students who show moderate symptoms may be able to perform relatively better than the students with severe anxiety who may often experience panic attacks.[23] General physical symptoms may include: headache, stomach upset, fear, feeling of dread, difficulty to breathe, increased sweating, weeping, flight of thoughts and blanking out. Students who suffer exam anxiety tend to be distracted during an examination, experience problem with comprehending relatively simple instructions and trouble organizing or recalling relevant information.

Adrenaline, which is released by the adrenal glands both in stressful and excited circumstances, is known to cause physical symptoms in pre-exam anxiety, such as increased heart rate, sweating, and rapid breathing etc.[25]

Pre-exam anxiety consists of:

- **Physiological over-arousal**: generally termed as **emotionality**. Physical symptoms include headache, stomach pain, diarrhea, nausea, shortness of breath, excessive sweating, giddiness or fainting, palpitation and dryness of mouth. Exam anxiety at times can also lead to panic attacks, wherein the student may experience a sudden intense fear, shortness of breath and extreme discomfort.
- **Dread and worry:** maladaptive cognitions. This includes catastrophic expectations of gloom and doom, fear of failure, irrational thoughts, feeling of inadequacy, self-condemnation, negative about self, frustration and comparing themselves with others.
- **Cognitive/Behavioral**: lack of concentration, freezing or going blank in the needful situation, conflict of thoughts, and inadequate organization. Difficult to concentrate leads to poor performance examinations. Becoming uneasy during and outright avoidance of the exam. Students usually report "blanking out" even though they have prepared well for the exam.[23] At times student may go in for substance abuse in order to overcome the emotionality and the sufferings.
- **Emotional**: depression, low self-esteem, anger, and feeling of hopelessness.[23]

One study reported that self-motivation and prayers, relaxation and sleep, music and TV, talking to friends and revising with them greatly were the most commonly taken measures by the students to reduce pre-exam anxiety. Some researches show data to support the effect of relaxation training and music in coping with anxiety.[26,27,28] Another study showed that few students also used harmful measures like smoking, drugs,

excessive intake of caffeine, under-eating or overeating while trying to win over exam anxiety which adds to the negative impacts of exam anxiety. Other reported measures were the internet usage, exercise, sports, and sharing with parents or teachers.

Conventional medicine suggests the usage of drugs for anxiety disorders work by inhibiting the threat detecting mechanisms of the body. Though there is no cure to anxiety disorders by usage of medication, it can be maintained under control. Generally used classes of drugs are Beta blockers, Benzodiazepines and Antidepressants. Other approaches towards combatting anxiety are via psychotherapies like cognitive behavioral therapy, mindfulness practices etc.

Alternative approaches include naturopathic therapies that include lifestyle management like proper nutritious diet intake, regular exercise, practice of yoga and relaxation techniques and acupuncture. Few available studies report the effect of acupuncture on pre-exam anxiety. Most of the studies are based on the effect of auriculo-acupuncture and wrist- ankle acupuncture on pre-exam anxiety.

Acupuncture is said to have originated in China. Acupuncture is a system of medicine wherein fine needles are inserted into the skin at specific points of the energy channels corresponding to the ailment. There are various strands of classical acupuncture theories and practice which all under a single strand called Traditional Chinese Medicine (TCM). Other styles like western medical acupuncture, Japanese acupuncture, Korean acupuncture, five element acupuncture and ear acupuncture are also available modalities.

This study is to analyze effectiveness of acupuncture in combatting pre-exam anxiety by comparing acute effects of two styles of acupuncture namely the classical five element acupuncture and western acupuncture. In Group 'A' (classical five element acupuncture group) 5 element Shu selection method (a part of classical diagnosis) was adopted to identify the personalized set of acupuncture points which were chosen for intervention. The point selection was individualized according to the complete symptoms presented by the subject one day before the examination. In Group 'B' (western acupuncture group) intervention was with specific set of previously proven acupuncture points those are effective for anxiety and anxiety related disorders. The effectiveness of the interventions are measured by statistically analyzing the outcome variables viz VAS- A, STAI Y-6 Questionnaire and physiological parameters like blood pressure and heart rate.

AIMS AND OBJECTIVES

2. AIMS AND OBJECTIVES

2.1 Aim

To investigate the anxiolytic effects of classical five element acupuncture in comparison to western acupuncture among B.N.Y.S medical students appearing basic science subjects during the 1st year university exams.

2.2 Objectives of the study

The objectives of the present study are to evaluate the effectiveness of classical five element acupuncture and western acupuncture by measuring:

- Visual analogue scale for anxiety
- State trait anxiety questionnaire form Y-6
- Blood pressure
- Heart rate

REVIEW OF LITERATURE

3. REVIEW OF LITERATURE

3.1 Introduction

Exam (or test) anxiety is a kind of situational anxiety and nervousness which is said to be a common difficulty faced by most of the university students.[29, 30] It withholds a student to express and prove his/ her true potential thereby lowering the performance in exam or other circumstances[31] Exam anxiety is a multidimensional framework that includes emotionality, worry, fear of failure, interference, lack of self-esteem and confidence.[32] One study reports that exam anxiety is regarded as one of the major complications among medical students as it is likely to cause low performance, underachievement, lack of motivation and psychological distress.[33] The exam anxiety is classified as a kind of social phobia in DSM-IV.[34]

3.2 INCIDENCE AND PREVALANCE:

3.2.1 AMONG SCHOOL STUDENTS:

The results obtained from a study conducted among 10^{th} and 12^{th} standard exam appearing students of Tamilnadu showed that majority of the board exam going students (74%) experience moderate level of anxiety which is in agreement with previous studies

conducted among school students. Further it has been reported that the anxiety levels experienced by 12th students are greater than 10th students.[35, 36]

Research reports that exam anxiety as one of the factors that affect achievement.[43, 44] Some of these studies have associated high test anxiety with low achievement.[43]

A study reports that 2 to 3 students in a given classroom irrespective of the standard experience high anxiety and 10 million elementary school children are not performing to their maximum capacity because of exam anxiety.[56]

Another research estimate that all students between 10% and 40% experience certain level of exam anxiety that can surface as early as seven years old, women, minorities, and the disabled are more likely to experience it.[57]

The prevalence of exam anxiety among school aged children has been reported to be between 10-41%.[60-62]

An author in 2001 reported that two thirds of students studying high school appeared to have experienced an uncomfortable level of exam anxiety which subsequently had a deleterious effect on their educational performance.[69]

3.2.2 AMONG COLLEGE/ UNIVERSITY STUDENTS:

One cross-sectional survey conducted at a private medical college in Pakistan reported that the prevalence of test anxiety among students of 1st year undergraduate student was 73.46% and that in 2nd year was 54.90%.[42]

Another research done among undergraduate medical students of Saudi medical school reported that about 65% of the students experienced test anxiety.[44]

The prevalence of exam anxiety among college going students has been reported to be between 15-20%.[63]

A study among students of healthcare profession reports that there is a larger percentage of students scoring moderately high or extremely high levels of exam anxiety ranging between 16.7–32.1% depending upon their study program.[65]

A study at MAHER University, Kanchipuram confirms the prevalence of noteworthy moderate levels of stress (VAS-A: 51%) among the first year MBBS students during exam.[70]

A study conducted to explore how exam anxiety affects performance of students in the science, particularly in Integral Calculus and Computational Methods, and established that low exam anxious students did better than high exam-anxious students on non-numerical and numerical tasks in Integral Calculus and Computational Methods.[45]

3.2.3 AGE

Anxiety disorders may develop at any age, but commencement usually occurs from childhood to adolescence, with limited people (< 1%) developing an AD after the age of 65 years.[82] A US-based study with 9282 sample stated the median age of inception of ADs to be 11 years.[83]

3.2.4 GENDER:

One study in Kerala reports that female students have higher exam anxiety levels than male students.[37]

Study reports from countries like Greece[38] and Romania[39] also show that female suffer greater magnitude of exam anxiety than male students.

A study among undergraduate educational psychology students at a Midwestern university states that female students have greater tendency to have higher levels of emotionality component thereby they experience higher levels of exam anxiety.[59]

One study among undergraduate medical students of Taibah University reported that female students experienced more stress due to extensive course load as compared with male students.[44]

Another study also showed that girl students have higher exam anxiety levels than boy students in tension, worry and physical symptoms but no difference in test-irrelevant thinking.[46]

A study conducted among 501 college freshers of an urban university reported that women students scored higher in both emotionality and worry, indicating a higher level of exam anxiety overall comparatively.[58]

Various studies reports that, regardless of cross-cultural settings and age, female students are likely to report higher levels of exam anxiety than male students[75, 76] The global occurrence of this phenomenon may reflect prevailing socialization practices which encourages women to express their emotions that men are anticipated to suppress or retain in themselves[69] ; otherwise, it may be a significance of the view that scholastic and

school work performance are not valued by men and that high academic performance is in some way not masculine[76] Another likely explanation for the gender differences is that the scales used to assess test anxiety might be less sensitive for males than for females.[10]

In contrary to the above reports one study done among exam appearing school students of Tamilnadu revealed that male students experience higher levels of exam anxiety compared to female students.[35]

A study conducted among high school students of Kolkata also reported that adolescent boys experience higher levels of test anxiety compared to girl students.[55]

3.2.5 PREVALANCE IN DIFFERENT CULTURES:

A Study compared the prevalence of test anxiety among students of Egypt, Brazil and the United States of America and found out that compared to the United States of America greater exam anxiety was found in students of Egypt on the dimensions of worry and emotionality whereas greater exam anxiety was found in the students of brazil but only in the emotionality dimension. Among the three greater arousability trait anxiety were reported in Egyptian students.[51]

The prevalence of exam anxiety among medical students of Malaysia as reported by an author to be 52%.[52] whereas in Pakistan it is 64%[53]

Another study conducted among University entrance exam appearing students of Turkey reported a prevalence of about 48.0% exam anxiety.[64]

A study conducted among the students 14 different countries reported that Korean students experience one of the highest levels of exam anxiety, whereas Japanese and Chinese students experience lowest levels of exam anxiety.[67]

On the Emotionality subscale and the Total Test Anxiety scale male students of Singapore scored higher than the male students of the US whereas female students of US scored higher than female students of Singapore.[68]

A study conducted in 2016 stated that test anxiety is more prevalent among students from Higher Institutions of Nigeria that negatively effect to their reduced academic performance.[72]

According to a study 45.9% of high school senior students in China suffer from severe exam anxiety.[77]

3.2.6 PREVALANCE IN RELATION TO FAMILY TYPE:

According to one study, family type is another parameter taken into consideration. Among the 100 student subjects, 53 came from nuclear families and their levels of anxiety was comparatively higher than the students who came from joint families. This may be because of the fact that students from small families receive cannot avail sufficient care and support from parents as well as relatives.[35]

3.3 THE CONSTRUCT OF TA:

Its study began at Yale University. Based on their responses to a Test Anxiety Questionnaire by Mandler and Sarason, groups of students were categorized as high- or low-test-anxious. On subsequent intelligence tests, the low-anxious students outperformed their high-anxious peers in both the scores and their variability.[98] As learning continued through successive trials of Block Design and Digit Symbol sub-tests, however, performance differences tended to disappear. the same study interpreted the difference in performance on the basis of learned psychological drives. Two kinds were said to be evoked by the test situation. First are task-directed drives. These stimulate behaviors to reduce the drive by completing the task. Second are learned anxiety drives. These stimulate two opposite and incompatible behaviors: (a) task-relevant efforts to finish the task and thereby to reduce the anxiety and (b) self-directed, task-irrelevant responses, manifested by "feelings of inadequacy, helplessness, heightened somatic reaction, anticipations of punishment or loss of status and esteem, and implicit attempts to leave the testing situation". Persons with strong anxiety drives are prompted to enact the task-irrelevant behaviors that impair performance. Low-test-anxious persons, less burdened by self-centered tendencies, can attend more easily to task-directed behaviors that enhance achievement. Theorists after Mandler and Sarason built on their behavioral interpretation:

- Proposing a bi-dimensional theory, Alpert and Haber in 1960 labeled the drives that lead to task-directed and task-irrelevant behaviors as facilitating and debilitating anxieties, respectively. Mandler and Sarason in 1952 had believed these constructs to be highly correlated; they devised their Test Anxiety

Questionnaire (TAQ) with only a debilitating scale and inferred the presence of one anxiety from an absence of the other. Alpert and Haber suggested that the constructs may be independent, such that "persons may possess a large amount of both anxieties, or of one but not the other, or of none of either". They provided a self-report instrument, the Anxiety Achievement Test, equipped with facilitating (AAT +) and debilitating (AAT-) subscales.

- From factor analyses of the TAQ, Liebert and Morris in 1967 proposed that debilitating test anxiety (hereafter called "test anxiety" or "TA") is itself bi-dimensional, consisting of the components worry and emotionality. Worry is "any cognitive expression of concern about one's own performance". Emotionality refers to autonomic reactions to the test situation, for example, perspiration and accelerated heartbeat. Liebert and Morris composed two scales to measure these components. Their experiments suggested that worry interferes with performance, but emotionality and performance are not related except for persons low on the worry component Morris & Liebert.
- The work of Liebert and Morris shifted TA theory toward a cognitive orientation. Wine in 1971 proposed an attentional theory to explain how TA harms performance: Test-anxious persons divide their attention between task-relevant activities and preoccupations with worry, self-criticism, and somatic concerns. With less attention available for task-directed efforts, their performance is depressed.
- Spielberger in 1972 has distinguished between two aspects of anxiety. A-State is "a transitory emotional state" of tension and nervous reaction, whereas A-Trait is a

chronic anxiety proneness characterized by A-State reactions in a wide range of stimulus situations. According to trait-state theory, TA is a form of trait anxiety[59]. High-anxious persons respond to testing with elevations in A-State (or emotionality). Worry is then triggered by the A-State manifestations. These latter reactions also activate random error tendencies. Hence, emotionality and worry both contribute to depressed performance.

- These theories all conceptualize an interference model of test anxiety, wherein TA disturbs the recall of prior learning and thus degrades performance. This model has been challenged by continuing reports (e.g., Tryon, 1980) that treatment can effectively reduce test anxiety but better performance usually fails to accompany TA reduction. An alternative deficits model of TA has been proposed, wherein "the lower test scores obtained by test-anxious students are attributable to inadequate study habits, or to deficient test-taking skills" (Tobias, 1985, p. 185). In this model, TA does not cause poor performance; the reverse is true. Awareness of poor past performance causes test anxiety.

3.4 AEOTIOLOGY OF EXAM ANXIETY:

The actual cause of symptoms in any anxiety disorder and its is underlying pathology is not well known or yet to be fully elucidated. It is thought that a complex combination of genetic, environmental, psychological and developmental factors contribute to the development of an anxiety disorder.[91] Several factors have been found to increase the risk of development of anxiety disorders.

There are four main quadrants of stresses reported that can contribute to test anxiety they are improper life style, lack of needed information, wrong style of studying and psychological factors.[47]

Many authors report that lifestyle related problems include lack of adequate rest, less physical activity, poor diet and low time management skills. These are the contributing factors to test anxiety.[48,49,18]

Studying all night before exam (28 students; 25.2%) and extensive course load (26 students; 23.4%) were the major confounding factors according to the study done among 5th year undergraduate medical students[44] and also among students of pharmD.[18]

One journal article concluded that fear of failure was an important trait component of exam anxiety which in exam situation is manifested as a circumstantial state component.[45]

Inability to study strategically i.e. poor style of studying through incomplete coverage of contents and night study before exams, inefficient preparation which includes lack of revising and review of syllabus material are important factors that can cause exam anxiety.[50]

Other factors include psychological factors like negative and irrational thoughts about examinations, exam outcomes, feeling of lack of control over the test situation with symptoms like blanking out during examination, [16, 17] perception of excessive course/ syllabus load.[18] The results of a study conducted among engineering college students in Hyderabad reported that cognitive factors (worry scale) are pivotal in creating anxiety comparatively more that the affective (emotionality) factors.[54]

That study at Maher University also analyzed various stressors causative to exam anxiety and stated that sedentary lifestyle, low to nil extracurricular activities contributed for 89%, academic factors accounted for 63% improper nutrition in food intake and skipping meals accounted for 59% and the psychological factors to 50% of anxiety during their exams of first year medical students.[70]

TABLE 3.1: Results of self-administered questionnaire filled by medical students to assess the factors for exam anxiety.[40]

FACTORS CONTRIBUTING TO EXAM ANXIETY	TOTAL	PERCENTAGE
Extensive course loads	109	90.8%
Lack of Physical Exercise	108	90%
Long duration of exams	93	77.5%
Inadequate rest	90	75%
Irrational thoughts about exams & outcomes	79	65.8%
No control over exam situation	77	64.2%
Not studying	77	64.2%
Memorize text book	73	60.8%
Negative thinking & self-criticism	63	60.8%
Improper nutrition	64	53.3%
Do not recall & review	50	41.7%
Studying all night before exam	29	24.2%

3.5 SIGNS AND SYMPTOMS OF TEST ANXIETY:

Anxiety in general prepares the mind cognitively, body physically and behaviorally to recognize and deal with the threats for survival.[71] The symptoms of exam anxiety may vary extensively and range from mild to severe.[73]

A student suffering from pre-exam anxiety can experience it in three dimensions that is physical, emotional and cognitive along with behavioural.[74]

Physical symptoms:

- Headache[25]
- Indigestion[25]
- feeling of fear[25]
- feeling of dread[25]
- shortness of breath[25]
- sweating[25]
- pacing or fidgeting[25]
- crying[25]
- racing thoughts[25]
- blanking out.[25]
- dizziness[78, 79,80]
- nausea[78,79,80]

3.6 PATHOLOGY OF PEA:

When there is perseverance of danger, various neurotransmitters and other chemical messengers, as well as hormones, are secreted which will modulate the neural circuitry concerned with the creation of fear, anxiety and other emotions.[92] The chief hormone involved in the ANS is the catecholamine 'epinephrine' (also known as adrenaline), which is produced by the adrenal glands. Adrenaline elicits a physical feedback to stress that includes amplification in respiratory rate and heart rate.[92] Simultaneously another hormonal system, the hypothalamic–pituitary–adrenal axis, initiates a trail involving numerous hormones and messengers. The termination of different signaling interactions is the release of adrenal hormones, the glucocorticoids, of which cortisol is the most important.[92,93] Cortisol causes a swift discharge of the body's energy stores to uphold blood sugar levels and also suppresses all other immune responses. Dysregulation of the HPA axis is identified to be associated with an increased risk of progress to major depression.[94] Moreover, the ageing brain is less able to downregulate the HPA axis and is more vulnerable to physiological stressors.[95] Therefore, in the elderly chronic anxiety can cause hyperactivity of this system, which can damagingly have an effect on memory and executive function. The major neurotransmitters concerned in anxiety disorders are noradrenaline, dopamine, serotonin and gamma-aminobutyric acid (GABA).[96] The finding that anxiolytic (anti-anxiety) drugs interact with neurotransmitters led to the proposal that abnormal activity in the brain is a physiological feature of anxiety.[91] Imaging of brain activity at the time of exposure to triggers of anxiety has suggested that the hippocampus and the amygdala have an integral

function in eliciting feelings of fear and anxiety.[91,96] The amygdale, which is located deep in the anterior medial section of each temporal lobe, is thought to be involved in communication and memory storage.[27] It is considered that the amygdala facilitates signal transfer between the components of the brain that process arriving sensory signals and those that infer the signals. An imbalance of the signaling pathway, possibly resulting from over activity of amygdala, is thought to add to excessive anxiety.[97] The amygdala works as a warning system, alerting for potentially impending threat and activating the nervous system to create feelings of fear or anxiety. The middle part of the amygdala is considered to accumulate emotional memories and, therefore, could have a part in the development of a specific phobia. Forming a part of the limbic system and located in the forebrain the hippocampus is the area of the brain that responds to stress and is important in spatial navigation and the configuration of memory.[91] The hippocampus is responsible for consolidating a traumatic or life-threatening event into a memory.

3.7 DIAGNOSIS OF PRE-EXAM ANXIETY:

The term ‘anxiety disorder’ comprises wide-ranging conditions that manifest with anxiety symptoms. Two main classification systems that are used as a foundation for distinction between the different kinds of ADs are the Diagnostic and Statistical Manual of Mental Disorders (DSM)[84, 85] and the International Classification of Diseases (ICD) by World Health Organization.[86] Till 2013, the DSM recognized 12 discrete AD that could be netted in seven headings:[84]

- Generalized anxiety disorder (GAD)
- Phobias, including simple (specific) phobias and social phobia (also known as social anxiety disorder or SAD)
- OCD
- Stress disorders, including acute stress disorders and post-traumatic stress disorder (PTSD)
- panic disorder (with or without agoraphobia)
- anxiety disorders owing to known physical causes (e.g. medical conditions and symptoms caused by drug misuse)
- Anxiety disorder not otherwise specified (covers symptoms not meeting the criteria for other anxiety disorders).

In 2013, the latest edition of the DSM (version 5) was released.[85] In the updated DSM, OCD is separated from the group of anxiety disorders and is presented in a distinct chapter together with related disorders. In addition to this the stress disorders (PTSD and acute stress disorder)are within the chapter covering trauma and stress related disorders. Separation of anxiety disorder and selective mutism, which had previously been classified as 'Disorders Usually First Diagnosed in Infancy, Childhood, or Adolescence', were added to the anxiety disorders.[87] An associated comment on the revisions highlights that the changes emphasize the distinct nature of the individual anxiety disorders, but that the chronological presentation of the chapters in the manual reflects the interconnectedness of the conditions. The ICD-10 distinguishes anxiety disorders under the general title 'Neurotic, stress-related and somatoform disorders', which comprises the subtitles of:[86]

- Phobic anxiety disorders (e.g. agoraphobia with or without panic disorder, social phobia and specific phobias)
- Other anxiety disorders (e.g. panic disorder, GAD, and mixed anxiety and depressive disorder)
- OCD
- Reaction to severe stress and adjustment disorders (acute stress reaction, PTSD and adjustment disorders)
- Dissociative (conversion) disorders (e.g. dissociative amnesia and dissociative stupor)
- Somatoform disorders (e.g. somatisation disorder and hypochondriacal disorders)
- Other neurotic disorders (e.g. neurasthenia).

Diagnosis of an anxiety disorder can be tricky, particularly in older people. Symptoms of anxiety can be analogous to those of other psychological conditions, such as depression, and the frequent presence of comorbid mental disorders further makes it difficult to diagnosis across all age groups.[88] Differentiating excessive anxiety from concerns around a recent distressing experience in older people, for example after a slip and fall, can also prove complex.[89] Anxiety in such situations might be expected by both the clinician and the patient and, thus, the diagnosis of an anxiety disorder may not be considered. Furthermore, some elderly people might have beliefs about emotional troubles that make them hesitant to raise concerns about anxiety and it has also been accepted that elderly from ethnic minority crowd often have different expression of anxiety. Both of these factors add to the complexity in recognizing anxiety in this age group.[87, 89]

Pre-exam anxiety can be diagnosed under the grouping of social phobia in the Diagnostic and Statistical Manual-IV. Social phobias are categorized by a clear and persistent fear of performance or social situations along with anxious expectation and avoidance where-in embarrassment may happen[69] which:

- Impedes considerably with the person's usual routine
- Interferes with academic/ occupational functioning/ relationships/ social activities.
- May have marked suffering about having the anxiety.[81]

3.8 SCALES FOR MEASURING PEA:

The State-Trait Anxiety Inventory (STAI):

- The State-Trait Anxiety Inventory (STAI) is a commonly used measure of trait and state anxiety (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983).[107]
- Form Y, its most accepted version, has 20 items for assessing trait anxiety and 20 for state anxiety.
- The Marteau and Bekker (1992) 6- item form consisted of items 3, 6, 17 (anxiety present) and 1, 15, 16 (anxiety absent) retaining the original scale's 2-factor model.[108]

Spielberger Test Anxiety Inventory

- Is the most extensively used, and for that reason is the international standard.
- Scores items both positive and negative, so that left and right response bias does not influence the scoring

- Scale picks up worry, which impairs performance, but also emotionality, better termed physiological arousal, which is only modestly related to impaired performance.

Westside Test Anxiety Scale (Richard Driscoll)

- Focuses strongly on performance impairments, with 6 of 10 items specifically about performance problems.
- Assesses worry, which impairs performance, but does not dwell on physiological arousal, which is only loosely related to performance.
- Is quick to administer and easily scored by the students themselves**.**
- Scale changes are found to be closely related to grade changes, suggesting that the scale is a sensitive register of anxiety impairments.
- Items are all scored positive, making it the scale easy to score but also vulnerable to left and right response bias.

Alpert-Haber 10 item Debilitative Anxiety Scale.

- One of the first to measures anxiety performance impairments.[99]
- This instrument consists of 2 scales and 28 items. These scales are: a 10-item Debilitating Scale (AAT-) and a 9-item Facilitating Scale (AAT+). The remaining 9-items are neutral.
- The subjects have to respond on a 5-point scale.

Cassady-Johnson Cognitive Test Anxiety Scale

- Focuses on the cognitive dimension of test anxiety, which impairs test performance.[59]

Children's Test Anxiety Questionnaire

- CTAQ is specifically designed to measure test anxiety in children 8–12 years of age.
- It provides scores for three dimensions of test anxiety: "worrisome thoughts concerning failure (i.e. 'when I take tests, I worry about failing'), automatic reactions concerning students' general and specific somatic indications of anxiety (i.e. 'when I take tests, my heart beats fast'), and off-task behaviours concerning nervous habits and distracting behaviours (i.e. 'when I take tests, I play with my pencil')[109]

Test Anxiety Inventory for Children and Adolescent

- The TAICA is a way to measure and assess test anxiety in children and adolescents in Grades 4 through 12.
- Those individuals who are being assessed rate their responses on a 5-point Likert-type scale ranging from 1 (never true about me) to 5 (always true about me).
- The TAICA is a 45-item self-report measure which consists of four sub scales.[110]

Irwin. G. Sarason Reactions to Tests (RTT) Scale

- Measures Tension; Worry; Test-Irrelevant Thinking; and Bodily Reactions.

- Is one of the early scales and has been used extensively in research.
- Contains 40 items, providing a thorough assessment but requiring more time to complete.[100]

Test anxiety questionnaire (TAQ)

- The first instrument to measure test anxiety was Test Anxiety Questionnaire.[98]
- It contains 42 items measuring students‟ own experiences before and during the examinations.
- The numbers of items in this questionnaire are 36.
- The students have to respond to all the items by placing a mark along a 15 centimeter line which is indicated by the midpoint and the endpoint.

Test Anxiety Scale (TAS)

- Sarason (1958) constructed the Test Anxiety Scale (TAS) consisting of 21 items.
- The students have to respond to the items by circling true and false[100]

Suinn Test Anxiety Behavior Scale (STABS)

- This instrument was constructed by Suinn (1969)[103]
- It consists of 50 items. The behavioral situations, which can cause test anxiety, are described in these items.
- Students have to respond to these 50 items on a 5-point scale.

Worry-Emotionality Questionnaire (W-E Q)

- Liebert and Morris (1969) developed the Worry-Emotionality Questionnaire (W-E Q)[104]
- This instrument consists of 10 items which have been modified for the immediate feelings and responses of the students.
- This instrument contains 5-items for Worry Scale and 5-items for Emotionality Scale.

Inventory of Test Anxiety (ITA)

- The Inventory of Test Anxiety (ITA) was developed by Osterhouse (1970)[105]
- It contains two subscales with 16 items: the Worry and Emotionality Subscales. Each scale is composed of 8 items.

State Test Anxiety Scale (STAS)

- This scale was developed by Hong (1998)[106]
- It consists of Worry and Emotionality Subscales. Both of these subscales require responses on a 4-point Likert-type scale.
- The range of score is from 4 to 16. The cognitive component of anxiety is Worry Subscale and physiological component is Emotionality Subscale in this instrument

Taylor Manifest Anxiety Scale:

- The TMAS is a test of anxiety as a personality trait, and was created by Janet Taylor in 1953 to identify subjects who would be useful in the study of anxiety disorders.[101]
- The TMAS originally consisted of 50 true or false questions a person answers by reflecting on themselves

In 2003, the Adult Manifest Anxiety Scale was introduced. It was made for three different age groups.[102] The AMAS takes into account age-related situations that affect an individual's anxiety.

Standardized screening questionnaires can initially be used to evaluate the presence and severity of anxiety. Validated screening tests include the Beck Anxiety Inventory, the Generalized Anxiety Disorder 7 (GAD-7) assessment and the Hospital Anxiety and Depression Scale.

3.7 Management of pre-exam anxiety

Several strategies can reduce test anxiety and increase your performance on test day.

Common strategies that may help combat pre-exam anxiety are:

- Learning how to study
- Study early and in similar places
- Establish a consistent pretest routine.
- Sharing with parents or teachers.

- Practicing relaxation techniques.
- Eating and drinking healthy.
- Regular physical exercise.
- Sound sleep

3.7.2 NON PHARMACOLOGICAL APPROACHES:

In spite of advancement in pharmacotherapy, many people did not receive optimal control over migraine. The growing risk of side effects of using medication has created an impact among the sufferers to find a remedy without using long-term medications. Even some experts indicated that the pharmacological therapy should only be applied if non-pharmacological management is ineffective.[116] Non-pharmacological treatments mainly aims at avoiding the triggers of migraine, like stress, weather, fasting, dietary factor and sleep and to reduce the frequency, duration and intensity. Some of the non-pharmacological approaches are Yoga, Acupuncture, Natural therapies, Psychological management, Physical management and other complementary therapies.

3.7.2.1 Yoga

Yoga ancient Indian Tradition, is now an emerging trend among the people across the world to keep oneself healthy. Yogic practices include physical postures, breathing practices and meditation which initiate mind body balance. This mind body balance effect has helped to reduce anxiety and depression even in chronic pain.[117,118]

A study suggests that pranayama seems to have a considerable positive effect on exam anxiety and performance and that it could be used as an easiest technique by students before their examinations, to reduce their exam anxiety and enhance their performance and result.[131]

An RCT conducted to evaluate the effectiveness of yoga and meditation in performance anxiety of young musicians reported that yoga groups presented a trend towards reduced performance anxiety and significantly low general anxiety, depression and anger relative to the control group.[111]

A review study based on a Korean journal concluded that physical interventions like yoga can help reduce anxiety.[112]

Yoga therapy also improved cardiac autonomic balance by enhancing the vagal tone and decreasing the sympathetic drive.[119]

3.7.2.10 Clinical researches in Acupuncture for exam anxiety

A study among the medical students of University of Greifswald, Germany concluded that auricular acupuncture as well as placebo intervention reduced exam anxiety wherein auricular acupuncture group had better improvement comparatively.[9]

Another study highlighted that Immediate stimulation of auricular pressing elevated heart rate variability among students with pre-exam anxiety and normal controls and that elevation of HRV potentially helps in treating pre-exam anxiety.

From reviewing these studies it is evident that acupuncture may be effective therapy for PEA. But, still it requires improvisation in designing the study and standardization in application.

3.8 ACUPUNCTURE AND PRE- EXAM ANXIETY

3.8.1 Traditional Chinese medicine

Traditional Chinese medicine (TCM) is one of the most ancient Chinese healing sciences known to human race. According to the World Health Organization and the National Institutes of Health (NIH), TCM originated more than 3000 years ago. The Huang Di Nei Jing or The Yellow Emperor's Classics of Internal Medicine, the most recognized classic encyclopedic compilation was published in the third century BC. Several dynasties of china contributed much to develop TCM. But in the middle, due to invasions and political changes TCM underwent ruin phase. Later due to strong political support, during 1960s and 1970s, the practice of TCM has grown at a spectacular pace. During this period practitioners faced certain difficulties, like qualitative source material of TCM were not readily available and the text were in Chinese language there was a genuine misunderstanding of many classic texts in TCM. Traditional Chinese Acupuncture is one the therapy in TCM, whose application is based on TCM theories.[120]

3.8.1.1 Philosophy of TCM

Traditional Chinese Medicine (TCM) emphasize on philosophic understanding of Yin –Yang (the bi- polarity) and the Five Element theory, according to which the whole universe function. As said

"Microcosm is the manifestation of macrocosm"

The above mentioned theories also explain the cause of health and illness in humans. The Other key concepts dealt with TCM includes the (Zang-Fu Visceral organ), Qi (energy), Blood, Body Fluid and meridian Theories.[121]

Most of the TCM's theories and principles are not based on human anatomy, but on human energy system. For example, Liver Qi stagnation, does not refer anatomically to the Liver organ as such, instead it refers to the energy flow of wood element and its representing zang organ liver.

3.8.1.2 Etio-pathology of TCM

TCM holds the view that health exists when there is a dynamic balance of Yin and Yang within the human body, and between the body and the external environment. Interruption of this balance results in disease. In general, the human body has the ability to resist itself from pathogenic factors from exterior and interior. This ability is due to the circulation of anti-pathogenic Qi, whereas disruption is caused by the pathogenic qi (pathogenic factors). The pathogenic qi enters the body only the interior and exterior factors go beyond human adaptability.

The 6 exogenous factors are wind, cold, heat, summer heat, dampness and dryness. And the 7 internal factors are joy, anger, melancholy, obsession, grief, fear and fright. The miscellaneous factors are irregular food intake, over-strain or lack of physical exercise, traumatic injuries, stagnation of blood and phlegm.[122]

3.8.1.3 Diagnosis and syndrome differentiation.

TCM holds the four diagnostic methods i.e, inspection, auscultation and olfaction inquiring and palpation. The signs and symptoms obtained from it are used to identify the cause. There are numerous methods of differentiating syndromes, of which three are majorly used. Differentiation of syndromes according to

- Zang- fu organs
- Eight principles : exterior-interior, heat-cold, excess-deficiency, yin-yang
- Theories of channels and collaterals[122]

3.8.1.4 Etio- Pathogenesis in Traditional Chinese Medicine:

Causative factors:

- Deficiency of qi and blood plus mental disturbance due to flight.
- Disturbance of heart by stirring of endogenous phlegm- fire.
- Perversion of harmful fluid due to dysfunction of the heart. In mild cases palpitation may be intermittent; in severe cases there may be continuous and uncontrollable throbbing of the heart.

Differentiation:

- Insufficiency of qi and blood: pallor, general weakness, shortness of breath, dizziness, disturbed sleep, blurring of vision, pale flabby tongue with teeth print on the edges, thread forceless pulse.
- Stirring of endogenous phlegm-fire: restlessness, irritability, dream disturbed sleep, yellow coating on tongue, rolling rapid pulse.

- Retention of harmful fluid: fullness of chest and epigastrium, expectoration of mucoid sputum, lassitude, white coated tongue, wiry rolling pulse.

3.8.1.5 Treatment of Anxiety in Chinese Medicine

Treatment in TCM is based on the diagnosis, which determines the deficient or excessive nature of a condition. The aim of treatment is to restore the balance of Qi and blood, Yin and Yang and the organs. In general, it is balancing and toning the deficient syndromes. Elimination and dispelling of the excessive pathogens restores the normality.

According the TCM principles treatment involves tonification of qi and blood, pacifying the endogenous phlegm fire and elimination of retained harmful fluids according to the need of the individual. In general, application of even pressure over the Back-shu and Front- mu points of the heart helps to calm down the heart.

3.8.2 Mechanism of Acupuncture: based on modern theories

Needling works by stimulating the nervous system, and its modes of action can be classified as:

- local antidromic axon reflexes
- segmental neuromodulation
- extra-segmental neuromodulation
- central nervous system effects myofascial triggers

3.8.2.3.1 Neuromodulators: opioid peptides

Opioid peptides are often referred as neuromodulators rather than neurotransmitters, due to its sustained effect they modify the activity of the target cell over a period of time. Four opioid peptides have been identified so far b-endorphin, enkephalin, dynorphin and orphanin. The concentrations of opioids differ in different areas throughout the CNS. B-endorphin is found in the brain and enkephalin in the spinal cord. Dynorphin, in the spinal cord and brainstem, has variable effects depending on the circumstances. Orphanin **[**also known as endomorphin or nociceptin**]** is widely distributed throughout forebrain, midbrain and spinal cord and has varied of functions in nociception, other sensory functions and autonomic control.[123]

An article suggests that anxiety disorders are related to a insufficient functioning of the endogenous opioid system. it also states that acupuncture placebo and other psychotherapies activates the endogenous opioid system.[114] Acupuncture has profound effect on b-endorphin and encephalin.

3.8.2.3.2 Non-opioid mechanisms in acupuncture

Serotonin is an important neurotransmitter in the stress control matrix. Serotonin activates the descending pain inhibitory systems in the brainstem, and leads to the release of more serotonin (as well as noradrenaline) in the dorsal horn.[124] Oxytocin has analgesic, anxiolytic and sedative effects during acupuncture.[125] Stroking, physical touch, particularly on the ventral surface of the body induce oxytocin.

3.8.2.4 Central regulatory effects:

Acupuncture enhance calming effect, improves wellbeing. Once the midbrain gets activated, the action potentials go on to trigger the brain centers, especially the cerebral cortex, hypothalamus and limbic system, the sites where 'regulatory' effects of acupuncture occur. Acupuncture has general calming effects on patients and improves wellbeing. Various central regulatory effects include:

- Autonomic balance: Studies have shown that acupuncture, in the short term, can reduce a raised blood pressure and increase a low blood pressure, and thus brings an autonomic balance.
- Regulates the hormonal system: Acupuncture stimulation may influence the anterior pituitary gland via the hypothalamus. This initiates the release into the circulation of both ACTH and b-endorphin, derivatives of single precursor, pro-opiomelanocortin. The arcuate nucleus of the hypothalamus is the site for gonadotrophin (GnRH) pulse generator, so acupuncture can affect the release of GnRH.
- Immune balance: Acupuncture has been found in some studies to enhance the immune system.[126] It can be generalized or localized autonomic changes regulating the lymph reticular system in the bone marrow and spleen, or circulation of b-endorphin, induces immune changes through leukocytic receptors.

3.8.3 Western acupuncture

Western acupuncture is a therapeutic modality derived from Chinese classical acupuncture that involves insertion of fine needles. WA uses current knowledge of medical anatomy, physiology and pathology, and follows the principles of evidence based medicine. Though WA has evolved from Chinese acupuncture, it doesn't adhere to the traditional concepts such as Yin/Yang and circulation of qi. It is considered as part of conventional medicine rather than a complete ''alternative medical system''.

3.8.3.1 Evolution of WA

Practice of acupuncture in UK started during the 19th century, doctors in the UK needled the maximal tender areas to relieve musculoskeletal pain. During 1970's Felix Mann, an eminent physician and trained acupuncturist declared: ''Acupuncture points and meridians, in the traditional sense, do not exist''. This created an agitation among conventional healthcare practitioners who could see their patients benefiting from needling, but suffered to explain the acupuncture mechanism scientifically, this created a surge of interest in the scientific approach to acupuncture. Eventually, acupuncture itself gained its credibility after the discovery of the release of opioid peptides during needling, and because of the formulation of the gate control theory.[127]

3.8.3.2 Acupuncture points

Text reference to the points used in the study[128,129]

TABLE 3.2 ACUPUNTURE POINTS FOR ANXIETY AND CHARACTERS

POINT	CHARACTER	INDICATION
GV 20	Calms Wind, pacifies Yang, benefits the Brain and sensory organs, calms the shen. Nourishes the Sea of Marrow; applying moxibustion raises the Yang.	Mental disorders, apoplexy, headache, dizziness, blurring of vision, tinnitus, nasal obstruction, rectal prolapse.
EX 6	Calms the shen, Alleviate pain, Calm Wind, Benefit the eyes and ears	wind stroke, epilepsy, headache, dizziness, generally relaxation.
GB 8	Expels Wind, benefits the head and ears, alleviates pain, harmonises the diaphragm and Stomach	Migraine, one-sided or unilateral headaches
GB 20	Eliminates Wind, benefits the head, clears the sensory organs Opens the channel With tonifying needle technique: strengthens the Marrow and the Brain	Headache, dizziness, common cold, pain in neck and shoulder, red and painful eyes.
EX 7	Eye brightening	Insomnia, dream-disturbed sleep. Eye Disorders, Tinnitus.

3.8.3.4 CHARACTERISTICS OF 5 ELEMENTS

The chart helps to diagnose and classify the elements from the symptoms presented by the patients (as done in classical acupuncture).

TABLE 3.3 CHARACTERISTICS OF 5 ELEMENTS[130]

ELEMENT	WOOD	FIRE	EARTH	METAL	WATER
Yin organ	Liver	Heart	Spleen	Lungs	Kidney
Energy flow time of yin organs	(1-3 am)	(11 am- 1pm)	(9- 11 am)	(3-5 am)	(5-7pm)
Yang organ	Gall bladder	Small intestine	Stomach	Large intestine	Urinary bladder
Energy flow time of yang	(11pm- 1am)	(1- 3pm)	(7-9 am)	(5-7 am)	(3- 5pm)
Sense	Sight	Words	Taste	Smell	Hearing

ELEMENT	WOOD	FIRE	EARTH	METAL	WATER
Nourishes	Muscles	Blood vessels	Fat	Skin	Bones
Expands into	Nails	Tongue	Lips	Body hair	Hair on head
Liquid emitted	Tears	Sweat	Saliva	Mucous	Urine
Bodily smell	Rancid	Scorched	Fragrant	Fleshy	Putrid
Temperament	anger	joy	Obsession	grief	Fear
Flavor	Sour	Bitter	Sweet	Hot	Salt
Sound	Shout	Laugh	Sing	Weep	Groan
Dangerous weather	Wind	Heat	Humidity	Dryness	Cold
Season	Spring	Summer	Mid Summer	Autumn	Winter
Color	Green	Red	Yellow	White	Black/ blue

Direction	East	South	Centre	West	North
Development	Birth	Growth	Transformation	Harvest	Store
Pain nature	Pulling pain	Pricking pain	Heaviness	Drilling pain	Radiating

MATERIALS AND METHODS

4. MATERIALS AND METHODS

4.1 Subjects

A total of 60 subjects both men and women with ages ranging between 17 and 18 participated in the study.

4.1.1 Description of the subjects including the selection of samples

The study subject were student volunteers from the Government Yoga and Naturopathy Medical College, Arumbakkam, Chennai District of Tamilnadu state in India. The subjects were recruited from the above mentioned college through screening done to assess inclusion and exclusion criteria. All the fifty seven subjects were 1st year B.N.Y.S students.

4.2 Ethical considerations

4.2.1 Ethical clearance

Ethical clearance was sought from the Institutional Ethical Committee prior to the start of the study and the approval for the same was granted.

4.2.2 Written Informed consent

Subjects who fulfilled inclusion criteria were informed about the purpose of the study and rights as research subjects. Informed consent form was administered in English. Adequate time was given to each subject to go through the information sheet and their queries were answered. Their right to withdraw from the study and the need for willingness to participate voluntarily in the study was explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent. (A sample information sheet and consent form is enclosed in Annexure)

4.3 Inclusion and Exclusion criteria

4.3.1 Inclusion criteria

The following inclusion criteria would be the basis for selecting the subjects:

- 1st year medical students at Government Yoga and Naturopathy medical college, Chennai.
- Appearing for basic science university exams.
- Baseline VAS for anxiety >15 points
- Without previous anxiolytic, sedative and/ or analgesic medication
- No former experiences with acupuncture
- No pregnancy or lactating

Exclusion criteria:

- Suffering from any other disease or disorder
- On any antipsychotic or antidepressant drugs
- Participating in another clinical trial
- Having family history of depression
- History of alcohol, smoking or drug addiction
- Participants unwilling to give informed consent.

4.4 Study design

4.4.1 Type of the design: A randomized trial

4.4.2 Randomization

Randomization was done using the online randomization tool at a website https://www.randomizer.org/ random numbers generation method was used.

4.4.3 Allocation of patients into study and control groups

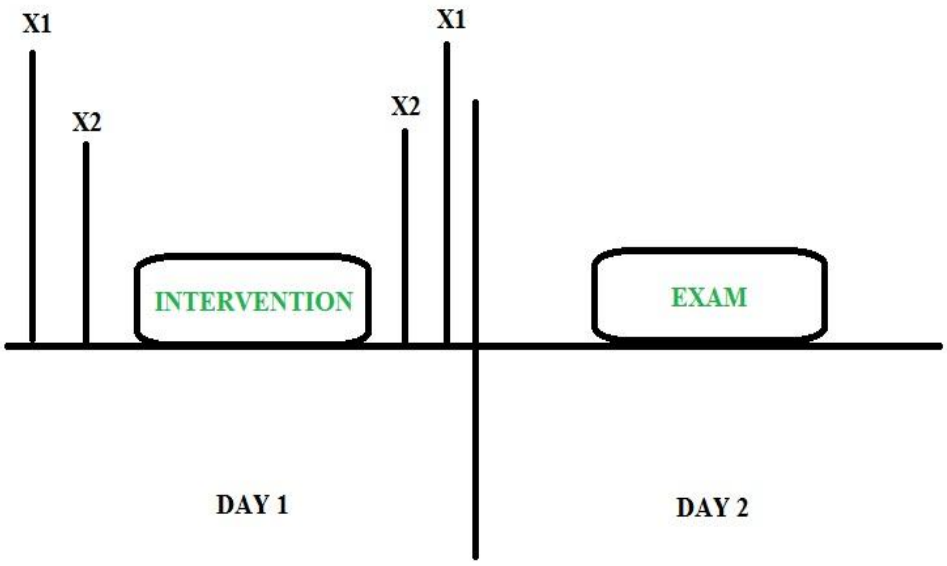
Patients were randomly allocated in Group A (classical five element acupuncture group) and Group B (western acupuncture group) in 1:1 ratio. 60 Subjects were initially screened and assigned to two groups. i.e., Group A (n= 30) and Group B (n= 30). Neither

the investigator nor the patients were blinded to the intervention. The subjects were not informed of the group they were taken in.

4.4.4 Data Points

One day prior to the date of examination the subject's pre-exam anxiety was measured. This is followed by the intervention in respect to the group they belonged and the style of acupuncture. Post intervention again the data were measured using the same scales.

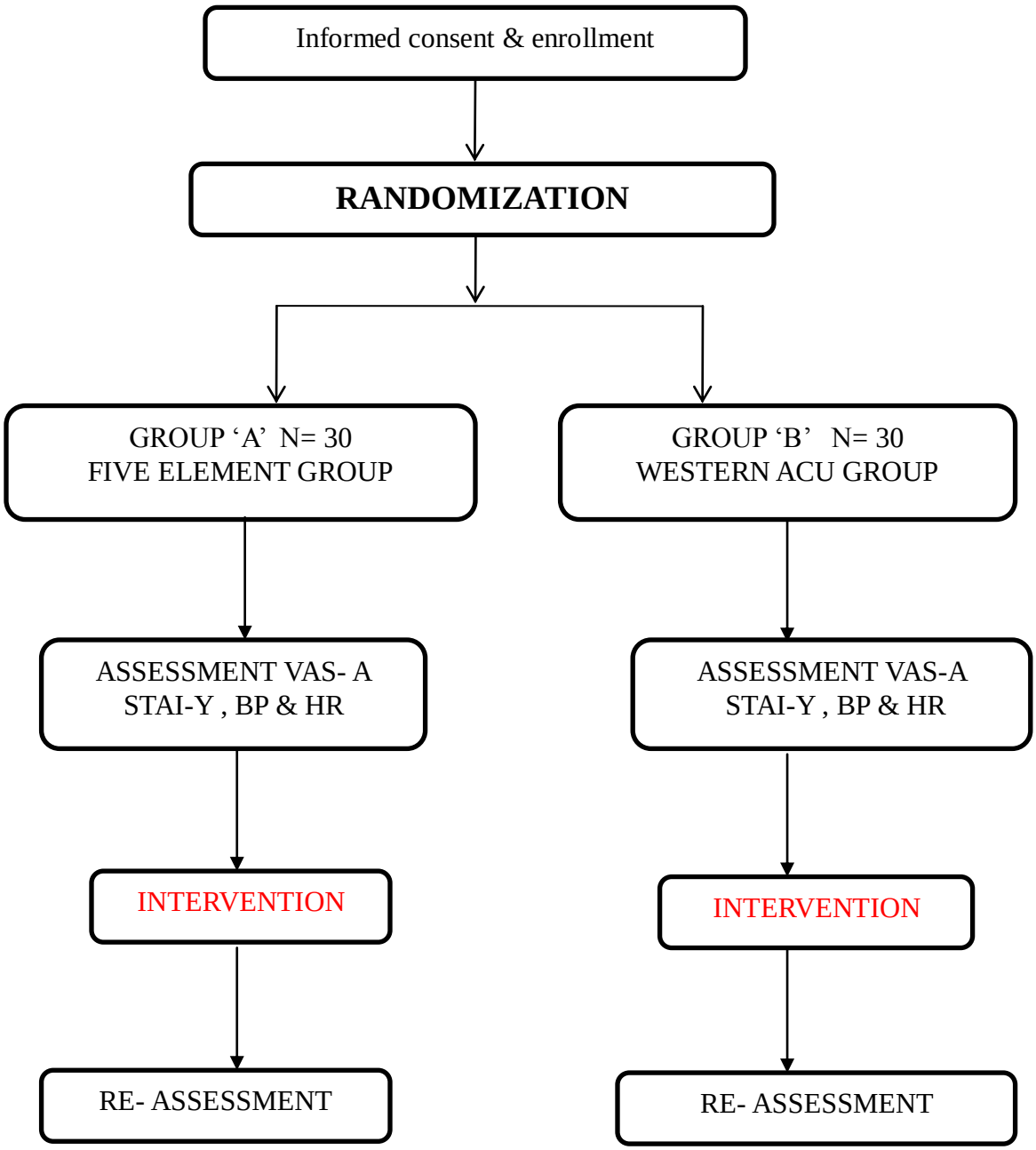
Figure ---: Illustration of Data points



X1: Heart Rate & Blood Pressure

X2: VAS- A & STAI Y-6

4.4.5 Trial Profile



4.5 Assessments:

The baseline and post-intervention assessments consisted of Primary and Secondary outcome variables.

4.5.1 Primary outcome variables

- Level of pre-exam anxiety using validated (VAS-A) Visual analogue Scale for anxiety (SCALE: 0-30 POINTS; where 0 = Calm & 30 = anxious)

4.5.2 Secondary outcome variables

- State and trait anxiety, using validated STAI (State-Trait-Anxiety Inventory) form Y-6
- Physiological parameters – heart rate (bpm), blood pressure (mmHg)

All the parameters were measured before and after intervention.

4.5.1.1 Intensity of anxiety:

Intensity of pre-exam anxiety was measured using Visual Analog Scale for anxiety (VAS) 30 point scale. It was administered prior intervention, one day before the examination, and 1 hour after the intervention.

VAS- Anxiety:

- The VAS-A is a validated scale which is a 100-mm horizontal line divided into 30 equal-sized partitions.[113] The left edge of the scale marked "calm" and the right edge marked "anxious (0= calm and 30= anxious)
- VAS—A is a single-item measure, also known as subjective units of distress, wherein subjects mark their subjective status on the visual scale.
- It is simple to afford and rapid in administration, and better understanding and completion rates.

SIX ITEM VERSION OF STATE TRAIT ANXIETY INVENTORY:

- This 6 item questionnaire was administered along with VAS-A ie., before the intervention and one hour after the intervention.
- It is a simplified version of STAI which is a 40 item questionnaire from which 1, 3, 6, 15, 16, and 17 items are only used in STAI Y-6

4.6 INTERVENTION

4.6.1 Group A (Classical Five element Acupuncture)

In this group 30 subjects after randomization were treated with classical five element acupuncture. Point's selection was done by "five element shu selection method". Needle was retained for a period of 20 mins. VAS was given to the subject for scoring before needling and 1 hr after the needles were removed.

4.6.1.1 Five element shu selection method:

In this method each and every symptom presented by the subjects are correlated with respective five elements based on their distinctive features and functions. Cumulatively the major element with its yin or yang polarity has been identified. Further, the selected element will be matched with the 'shu group (1-5) – which is grouped according to the functions', based on this a point is selected from 60 points of command. Along with the selected point supportive points like yuan source, xi-cleft, back-shu, front-mu points are used according to the need.

Single shu point and an average of 3-5 needles for supportive points were used.

The aim of five element acupuncture is to eliminate the pathogenic factor (8 factors according to acupuncture) and strengthening the affected element.

Eg: If Patient present symptoms like

- c/o headache on the temple area of the head – (headache belongs to wood element, sides of the head represents GB meridian).
- c/o Pulling pain around the left eye – (pulling nature represents wood, eye organ is related with wood element)
- c/o Pain in left side of the neck – (SI meridian passes over the sides of the neck)
- c/o Vomiting sensation – (it represents wood and earth element)

The majority of symptoms reveal the imbalance in the wood element and disturbance in qi flow. Along with it gastro- intestinal disturbance is present, which is related to the 5^{th} group of the Shu table. All the symptoms are acute and external and represents yang imbalance. Therefore GB meridian of wood element whose 5^{th} group point from

Shu table (i.e.) GB 34 is selected and needled. This corrects the imbalance among the elements. Later, to strengthen the meridian source point of GB can be given bilaterally. This approach identifies the root cause of the condition and helps to treat accurately.

Table 4.1 :Shu points , Anton Jayasuriya. [163,164]

	G.B.	S.J.	U.B.	S.I.	St.	L.I.		Liv.	P.	K.	H.	Sp.	Lu.	
Metal	44	1	67	1	45	1	Jing-Well 1	1	9	1	9	1	11	Wood
Water	43	2	66	2	44	2	Yung-Spring 2	2	8	2	8	2	10	Fire
Wood	41	3	65	3	43	3	Shu-Stream 3	3	7	3	7	3	9	Earth
Fire	38	6	60	4	41	5	Jing-River 4	4	5	7	4	5	8	Metal
Earth	34	10	54	8	36	11	He-Sea 5	8	3	10	3	9	5	Water

Group 1	Emergency conditions like cardiac arrest, respiratory arrest
Group 2	Febrile conditions
Group 3	Heaviness sensation, rheumatism, laziness, Psorisais
Group 4	Heat and cold disorder
Group 5	QI disorders, GI abnormalities, All skin diseases

4.6.2 Group B (Western Acupuncture)

In western acupuncture style pre- determined set of acupuncture points were given for a period of 20 mins. VAS was given to the patient for scoring before needling and 1 hr after removing the needle.

Table 4.2: Points used for group B (Western acupuncture group)

GV 20(BAIHUI)
EX 6 (SISHENCONG)
GB 8 (SHUANIGU)
GB 20 (FENGCHI)
EX 7 (YIMING)

4.6.3 Needling

Needling methods for both groups were same.

- Both groups were treated with 'use and throw' stainless steel needles.
- Needles with the measurement of 0.25 * 0.25 were used throughout the study.
- Sterile measures were adopted and used needles were carefully disposed.
- Needles were inserted till the level where the sensation of presence of needle was perceived by the subject or at the level where deqi (arrival of qi) is elicited

4.7 Data Extraction:

- Data were collected as self-reported observations using primary outcomes and secondary outcome variables.
- Baseline data were obtained on the day before examination.
- After randomization and respective interventions post data were obtained 1 hour after the intervention.
- Data were organized in Microsoft Excel sheets (version 2010)

RESULTS

5. RESULTS

The present study was conducted to compare and evaluate the acute effect of classical five element acupuncture and Western Acupuncture on pre-exam anxiety of 1st year B.N.Y.S students. The effectiveness of intervention were assessed based on the outcome variables viz 30 point VAS-A score, blood pressure, heart rate and STAI Y-6 questionnaire

The primary outcome variable was measured using 30-point VAS-A score, taken before and after intervention one day before the examination. The secondary outcome variables were blood pressure, heart rate and STAI Y-6 questionnaire administered along with VAS-A

The measured outcome variables were statistically analyzed using SPSS software – version 16. PAIRED T-TEST was used to assess the outcome.

5.1 Primary outcome: Both the groups are statistically significant in reducing intensity anxiety ($p < 0.001$), however on observing t value Group A showed better improvement than Group B.

5.2 Secondary outcome: Analysis of blood pressure both systolic and diastolic showed statistically significant changes in both groups. However on observing the t value, Group A showed better improvement than group B in lowering both systolic and diastolic blood

pressure. Heart rate also showed statistically significant changes in both the groups and t value was higher in group A compared to group B

On analyzing STAI Y-6 Questionnaire, there results were statistically significant in both the groups.

5.3 Demographic details among the subjects recruited:

A total of 60 subjects participated in the study. In which Group A had 30 subjects (Female: 24; Male: 6) and Group B received 30 subjects (Female: 23; Male: 7).
The recruited subject's age ranged between 17- 18 years. All the subjects were students and unmarried.

5.5 Descriptive Statistics:

Table 5.1: Descriptive statistics

	N	MINIMUM	MAXIMUM	MEAN	STD. DEVIATION
AGE	60	17	18	17.9	0.30

5.6 PRIMARY OUTCOME:

TABLE 5.2: Mean, S.D and t-value of VAS-A between pre-test & post-test among group A

GROUPS		N	MEAN	SD	T- TEST
Group A	Pre- test	30	26.03	2.54	**36.4769**
Group A	Post- test	30	5.83	1.86	

Fig: 5.1 Pre & Post VAS- A Score of Group A

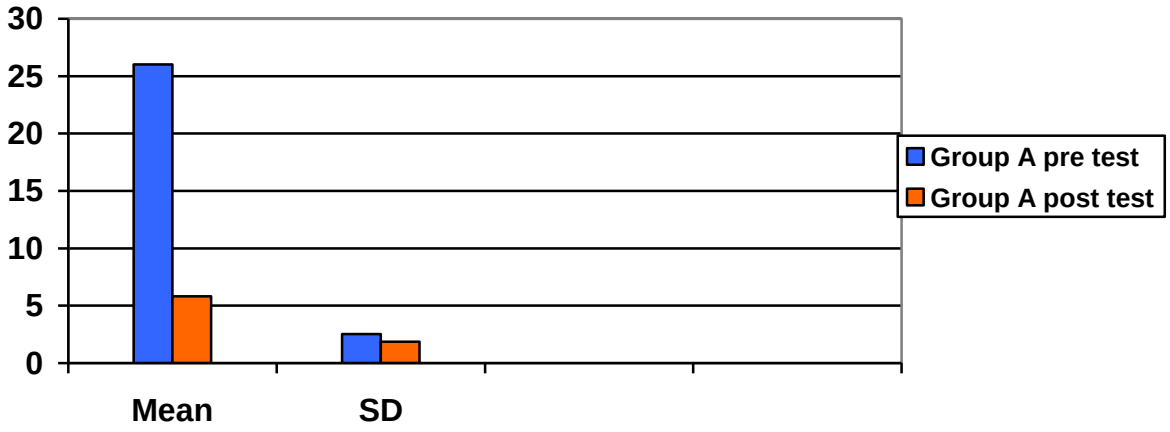


TABLE 5.3 : Mean, S.D and t-value of VAS-A between pre-test & post-test among group B

GROUPS		N	MEAN	SD	T- TEST
Group B	Pre- test	30	26.70	1.84	**15.1434**
Group B	Post- test	30	10.57	5.46	

Fig: 5.2 Pre & Post VAS-A Score of Group B

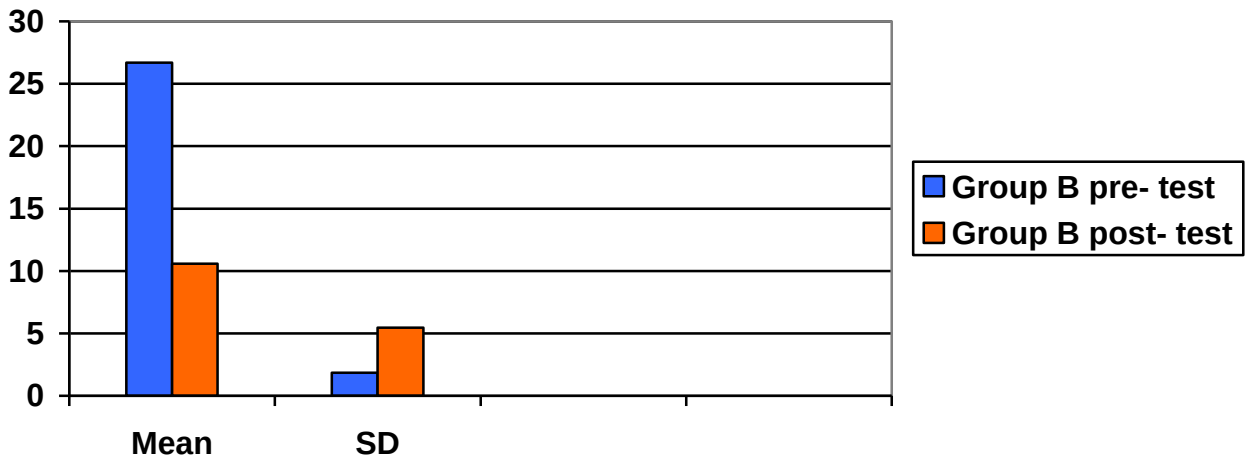


TABLE 5.4: VAS-A SCORE PRE & POST BETWEEN TWO GROUPS

GROUPS	VAS- A	N	MEAN	SD	T value	P value
GROUP A	Pre	30	26.03	2.54	**36.4769**	**<0.0001**
	Post	30	5.83	1.86		
GROUP B	Pre	30	26.70	1.84	**15.1434**	**<0.0001**
	Post	30	10.57	5.46		

Table shows difference in magnitude of anxiety among both groups. Data collected using VAS-A tool before and after intervention.

The observed value between pre and post VAS-A scale in both groups showed significant changes. However on observing the difference in the mean, SD of pre and post scores and the T value in both groups, Group A showed better reduction in magnitude of anxiety.

Fig 5.3 VAS-A score of pre & post intervention- Group A

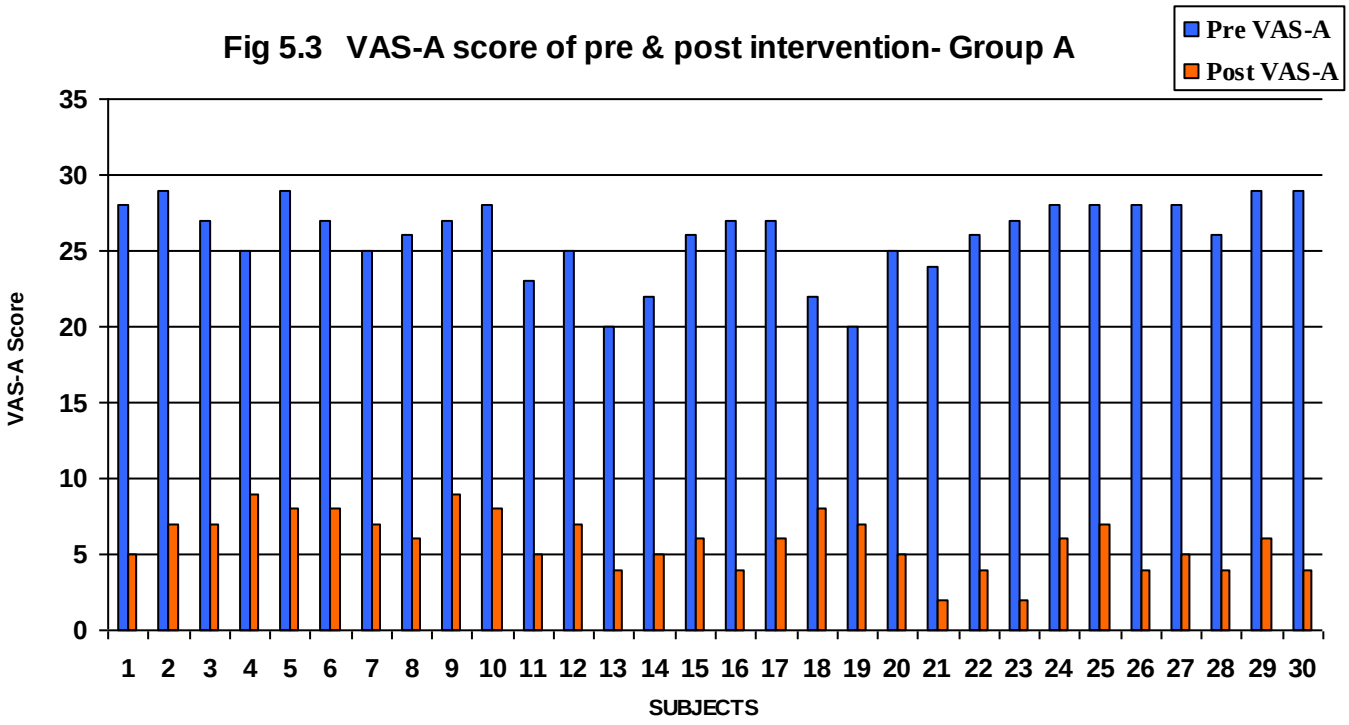
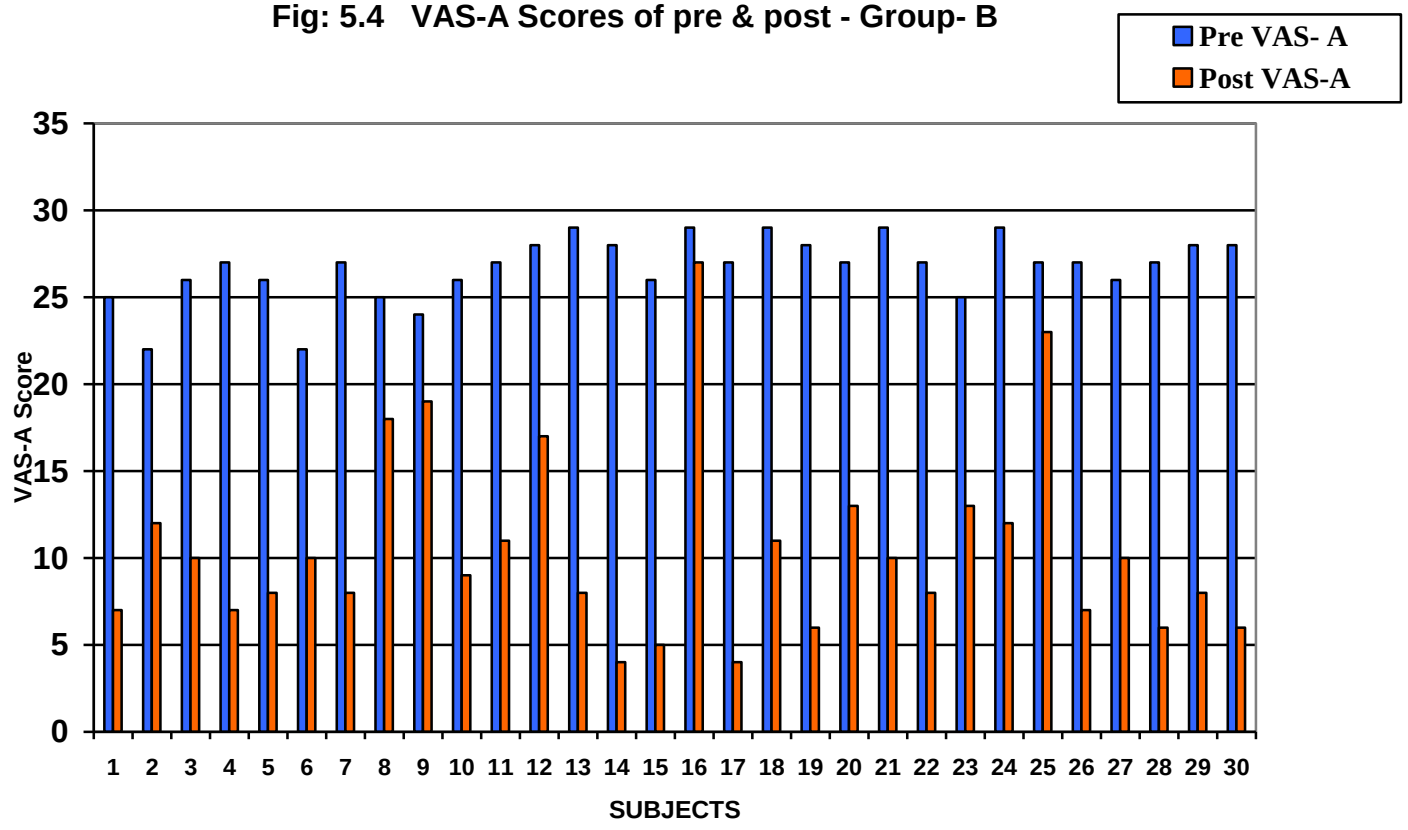


Fig: 5.4 VAS-A Scores of pre & post - Group- B



5.7 SECONDARY OUTCOME:

BP SYSTOLIC

TABLE 5.5: Mean, S.D and t-value of pre & post SYSTOLIC BP among group A

GROUPS		N	MEAN	SD	T VALUE
Group A	Pre	30	137.60	5.67	14.8893
Group A	Post	30	122.27	2.72	

The two-tailed P value is less than 0.0001.

Fig: 5.5 Mean & SD of pre & post Systolic BP- Group A

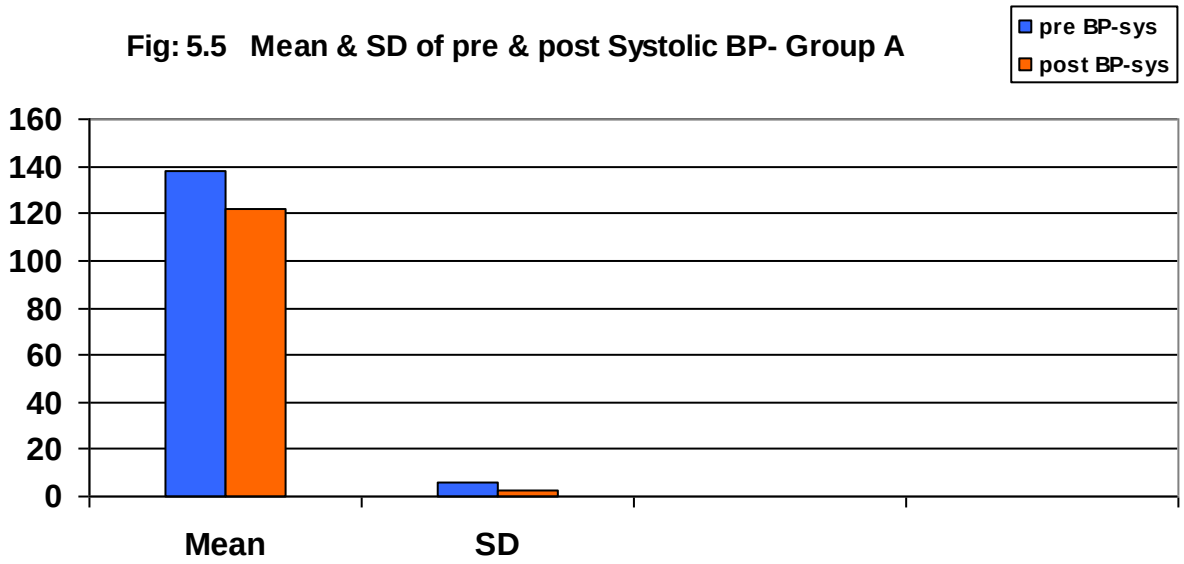


TABLE 5.6 : Mean, S.D and t-value of pre & post SYSTOLIC BP among group B

GROUPS		N	MEAN	SD	T VALUE
Group B	Pre	30	136.97	5.82	8.5056
Group B	Post	30	126.07	4.46	

The two-tailed P value is less than 0.0001.

Fig: 5.6 Mean, S.D of pre & post SYSTOLIC BP among group B

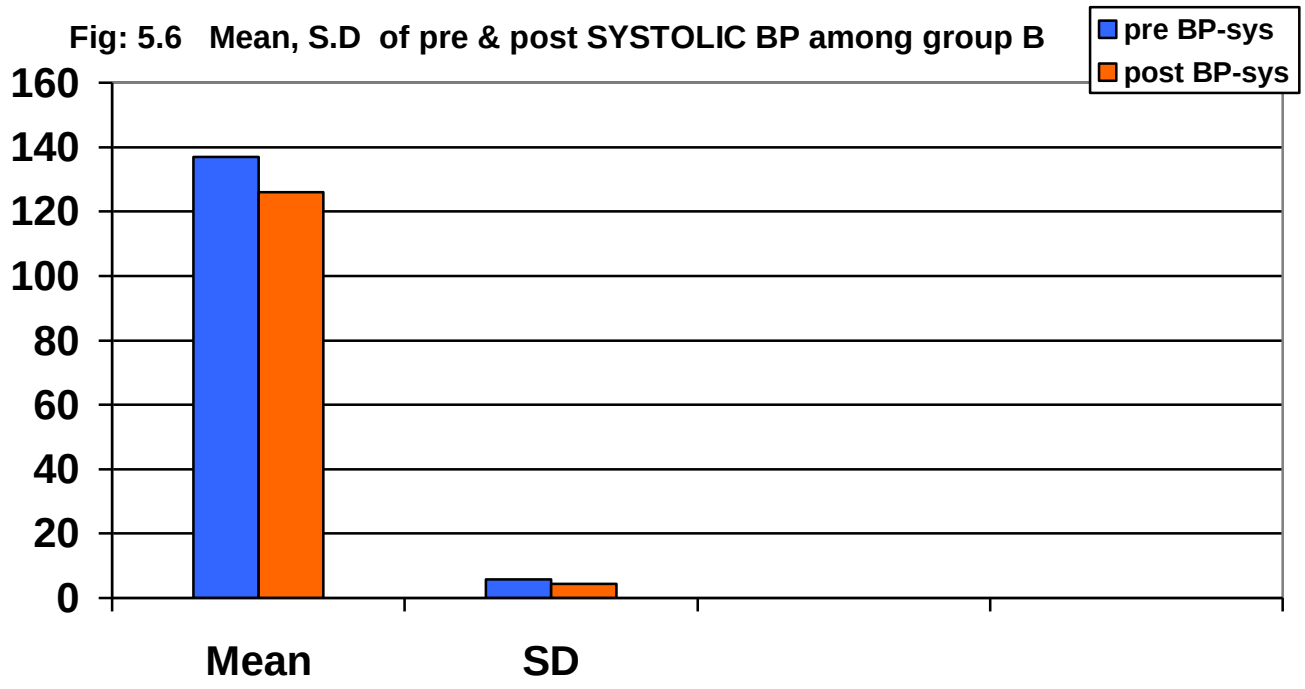


TABLE 5.7: PRE & POST SYSTOLIC BP VALUES BETWEEN TWO GROUPS

GROUPS	BP- SYS	N	MEAN	SD	T value	P value
GROUP A	Pre	30	137.60	5.67	14.8893	<0.0001
	Post	30	122.27	2.72		
GROUP B	Pre	30	136.97	5.82	8.5056	<0.0001
	Post	30	126.07	4.46		

The observed value between pre and post systolic BP scale in both groups showed significant changes. However on observing the difference in the mean, SD of pre and post scores and the T value in both groups, Group A showed better reduction in systolic BP.

BP DIASTOLIC

TABLE 5.8: Mean, S.D and t-value of pre & post DIASTOLIC BP among group A

GROUPS		N	MEAN	SD	T VALUE
Group A	Pre	30	87.53	3.81	11.2267
Group A	Post	30	80.67	2.54	

The two-tailed P value is less than 0.0001.

Fig: 5.7 Mean & S.D of pre & post DIASTOLIC BP among group A

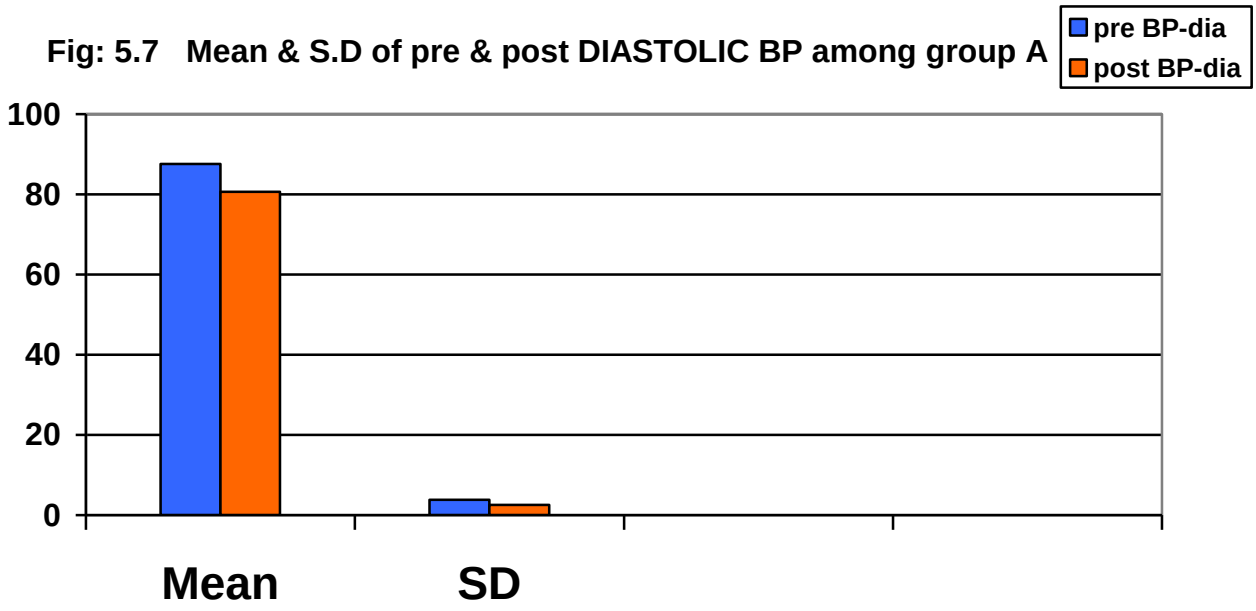


TABLE 5.9: Mean, S.D and t-value of pre & post DIASTOLIC BP among group B

GROUPS		N	MEAN	SD	T VALUE
Group A	Pre	30	87.40	2.79	6.2768
Group A	Post	30	84.53	2.40	

The two-tailed P value is less than 0.0001.

Fig: 5.9.a Mean and S.D of pre & post DIASTOLIC BP among group B

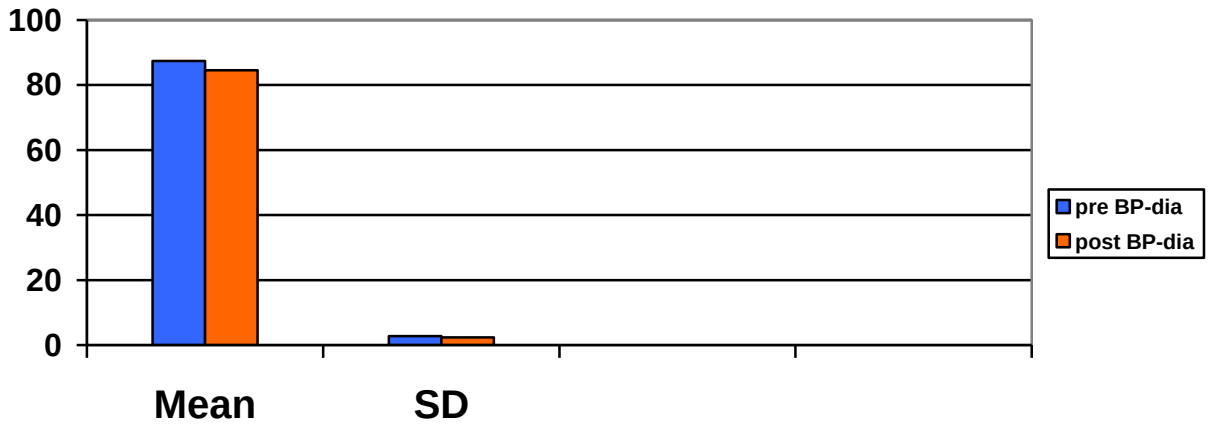


TABLE: 5.9.A PRE & POST DIASTOLIC BP VALUES BETWEEN TWO GROUPS

GROUPS	BP-DIA	N	MEAN	SD	T value	P value
GROUP A	Pre	30	87.53	3.81	11.2267	<0.0001
	Post	30	80.67	2.54		
GROUP B	Pre	30	87.40	2.79	6.2768	<0.0001
	Post	30	84.53	2.40		

The observed value between pre and post diastolic BP scale in both groups showed significant changes. However on observing the difference in the mean, SD of pre and post scores and the T value in both groups, Group A showed better reduction in diastolic BP.

PULSE RATE

TABLE 5.9.b: Mean, S.D and t-value of pre & post HEART RATE among group A

GROUPS		N	MEAN	SD	T VALUE
Group A	Pre	30	93.87	5.32	19.1269
Group A	Post	30	73.00	2.18	

The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Fig: 5.9.b Mean & SD of pre & post HR among Group A

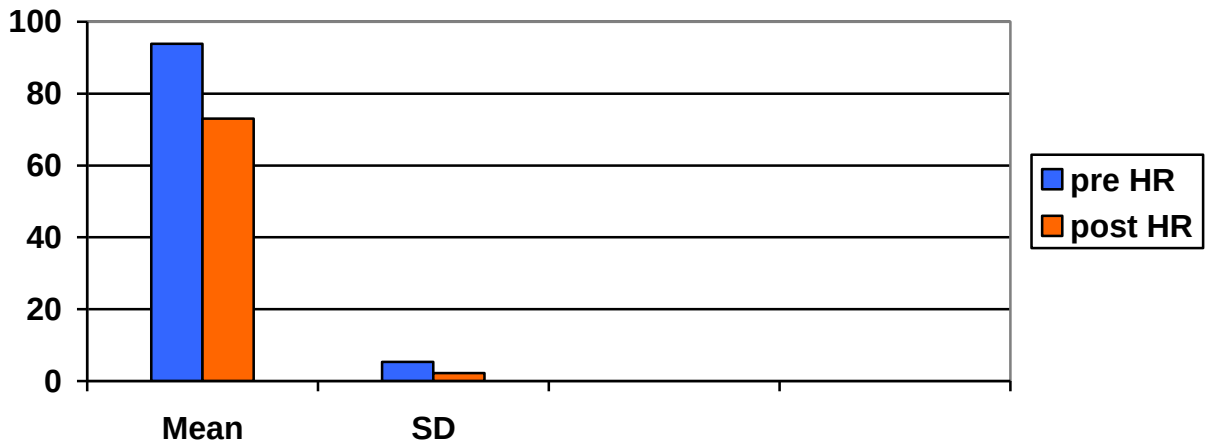


TABLE: 5.9.c Mean, S.D and t-value of pre & post HEART RATE among group B

GROUPS		N	MEAN	SD	T VALUE
Group B	Pre	30	92.97	5.73	10.3123
Group B	Post	30	77.47	6.94	

The two-tailed P value is less than 0.0001.

Fig 5.9.c Mean & SD of pre & post HR among Group B

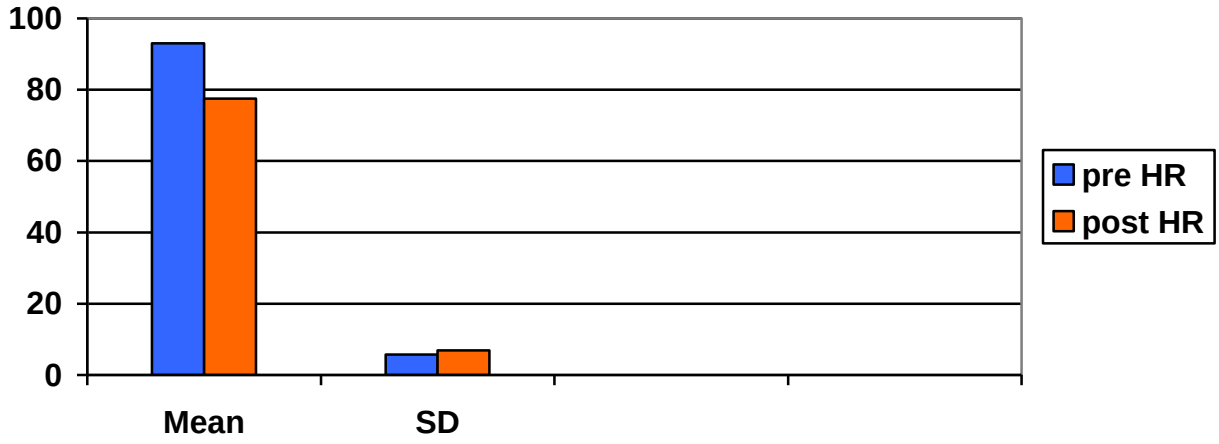


TABLE 5.9.d PRE & POST HEART RATE VALUES BETWEEN TWO GROUPS

GROUPS	HR	N	MEAN	SD	T value	P value
GROUP A	Pre	30	93.87	5.32	19.1269	<0.0001
	Post	30	73.00	2.18		
GROUP B	Pre	30	92.97	5.73	10.3123	<0.0001
	Post	30	77.47	6.94		

The observed value between pre and post Heart rate in both groups showed significant changes. However on observing the difference in the mean, SD of pre and post scores and the T value in both groups, Group A showed better reduction in heart rate.

STAI- Y

TABLE 5.9.e: Mean, S.D and t-value of pre & post STAI- Y Score among group A

GROUPS		N	MEAN	SD	T VALUE
Group A	Pre	30	66.4413	6.0089	28.6859
Group A	Post	30	28.8957	4.4006	

The two-tailed P value is less than 0.0001.

Fig 5.9.d Mean & SD of pre & post STAI-Y among Group A

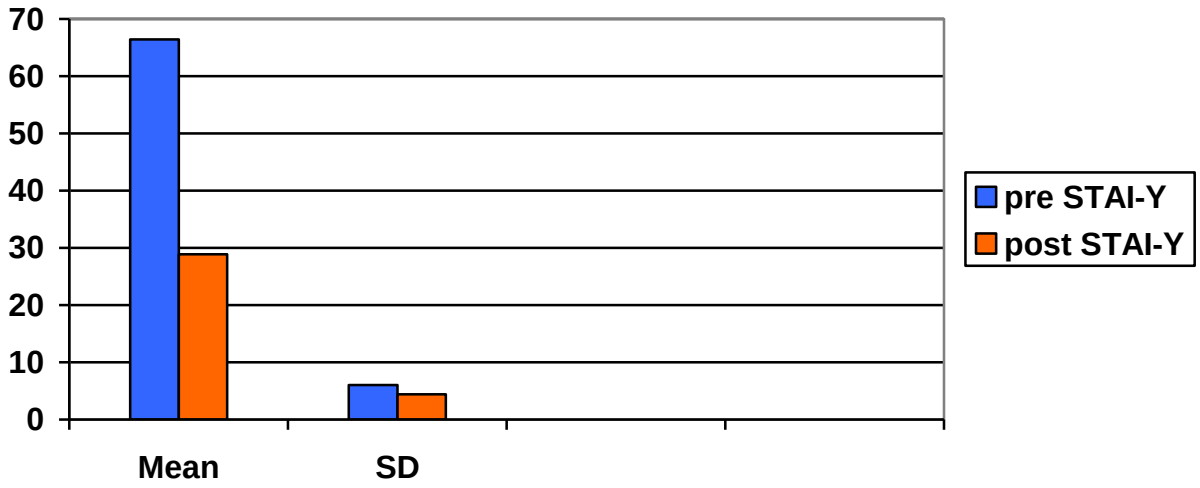


TABLE5.9.f : Mean, S.D and t-value of pre & post STAI- Y Score among group B

GROUPS		N	MEAN	SD	T VALUE
Group B	Pre	30	65.0867	7.2053	16.1202
Group B	Post	30	35.7750	11.1734	

The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant.

Fig: 5.9.e Mean & SD of pre & post STAI-Y among Group B

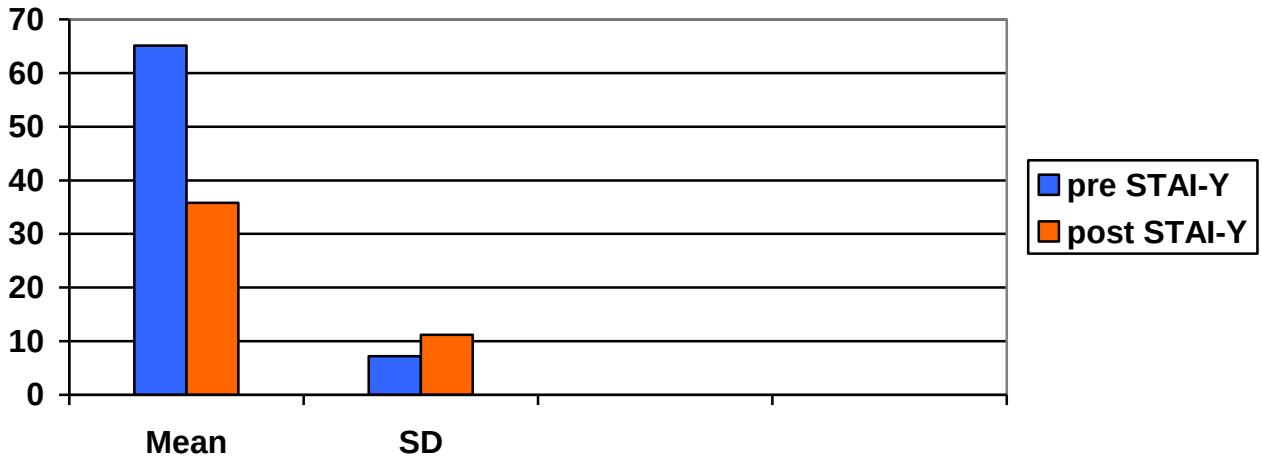


TABLE 5.9.g PRE & POST STAI-Y VALUES BETWEEN TWO GROUPS

GROUPS	HR	N	MEAN	SD	T value	P value
GROUP A	Pre	30	66.4413	6.0089	28.6859	<0.0001
	Post	30	28.8957	4.4006		
GROUP B	Pre	30	65.0867	7.2053	16.1202	<0.0001
	Post	30	35.7750	11.1734		

The observed value between pre and post STAI-Y scores in both groups showed significant changes. However on observing the difference in the mean, SD of pre and post scores and the T value in both groups, Group A was superior.

DISCUSSION

6. DISCUSSION

Pre- Exam anxiety is the major psychological stressor faced by the students of all ages. It is seldom recognized as a problem to seek medical help but has a spectrum of detrimental effects upon student's psychological well-being and performance in exam.

In the current study, the effectiveness of classical five element acupuncture and western acupuncture on pre-exam anxiety was compared. Points used to treat Western Acupuncture group were GV 20, EX 6, GB 8, GB 20 and EX 7. Each point has its own character and action which helps to reduce the anxiety levels of the subject, this has been explained Table 3.1.

Method adopted to treat Group A was 5 element shu selection. On reviewing prior studies on pre exam anxiety, trials were conducted using only verum acupuncture (Chinese acupuncture) with specific set of points. To my knowledge studies involving TCM diagnosis and providing individualized treatment were very few.

A study by Jerusa A.A et al stated "results of their pilot study used individualized treatment in real acupuncture group, seem to offer best approach. It takes into account all clinical signs and symptoms presented by each patient."[132] Therefore in this study also TCM diagnosis and individualized treatment was given to the subjects in Group A (classical five element group).

Table 5.4 reveals that both groups help in significant reduction of anxiety intensity ($P > 0.001$). In group A and the major element disturbed was corrected and tonified where as in Group B correction of imbalance in elements weren't done. However the change in intensity of anxiety may be due to specific action of these individual points.

This calming and relaxing effect of acupuncture can be explained to some extent with the hypothesis from previous studies. A study states that patients suffering from anxiety exhibited parasympathetic hypo-function, autonomic nerve dysfunction and sympathetic hyperfunction.[115] The results discussed above suggest that the treatment may have enhanced the regulatory ability of the autonomic nervous system, possibly by increased vagal nerve excitability.

According to TCM, the predominant symptoms of anxiety are fear, shortness of breath, disturbed sleep, dizziness, irritability, forgetfulness, restlessness and headache which are related to disturbance of water, fire and wood elements. In this study's classical group, the points selected to the patients vary among the elemental points of these three elements along with few in earth element.

Supporting the involvement of water, fire and wood elements, it was stated by Wocao Wu et al that pre-exam anxiety is majorly associated with heart, liver and kidney function.

Table 5.9h shows the anxiety scales of STAI-Y showed significant changes in both groups. However on observing the difference in the mean, SD of pre and post and t value in both groups, Group A showed better improvement than group B.

Analysis of physiological parameters among both groups, the observed value between pre and post intensity showed significant changes in both the groups. (Group A P <0.0001 and Group B P <0.0001]. Though both group treatments among the groups are significant Group A showed better changes than Group B.

On the whole, patients in the classical five element group showed significant improvement in the reduction of magnitude of anxiety than western acupuncture group. The betterment was also observed in physiological parameters of blood pressure and heart rate.

6.1 LIMITATIONS OF THE STUDY

This study has a number of limitations including generalizability. The population of female students is significantly more in naturopathy medical colleges therefore they were the majority in the participants of this research which could bias the results. Future studies should use larger sample size, qualitative measurement of anxiety levels and comparison of group of students with higher and lower anxiety levels for contributory factors to validate the results.

6.2 FUTURE DIRECTION OF THE STUDY

Study can be conducted with larger sample size and among students attending competitive and other future deciding examinations especially 10^{th} and 12^{th} standard exams.

CONCLUSION

7. CONCLUSION

This study has revealed that both styles of acupuncture viz., Classical five element and Western Acupuncture are effective in reducing anxiety levels in students appearing for exam with the former more effective comparatively. This study demonstrates that the energy physiology of Classical five element Acupuncture are more subtle and needs deeper understanding as it is skeptical to implement without proper knowledge. It primarily aims at correcting the fundamental five element imbalances upon which any illness can be treated effectively. On contrary over simplification of clinical Acupuncture though easy and effective in conditions like pain relief, it has limited the effectiveness of Acupuncture in correcting the fundamental imbalances. Further study in a larger sample would enhance accuracy.

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ANNEXURES

INFORMATION SHEET

We are conducting a study "ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY" at Government Yoga and Naturopathy Medical College Hospital, Chennai – 106.

The purpose of this study is to evaluate the effectiveness of five element and western acupuncture in helping cope with pre-exam anxiety. We need your participation in this study.

The privacy of the participants in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefit to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of investigator

Signature of participant

Date:

INFORMED CONSENT FORM

Title of the study:

"ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY"

Name of the Participant:

Name of the Principal Investigator: Dr. VIJAYAKUMAR MONICA

Name of the Institution:

Government Yoga & Naturopathy Medical College,

Chennai – 600 106

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am exercising my free power of choice; hereby give my consent to be included as a participant in "ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY"

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I have not participated in any research study within the past _____month(s).

9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

12. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

13. I have understood that my identity will be kept confidential if my data are publicly presented.

14. I have had my questions answered to my satisfaction.

15. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature_____

Date_____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature_____

Date_____

Address and contact number of the impartial witness:

Name and Signature of the investigator or his representative obtaining consent:

Name _____ Signature_____

Date_____

INFORMATION TO PARTICIPANTS

Investigator: Dr. VIJAYAKUMAR MONICA

Name of Participant:

Title:

"ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY"

You are invited to take part in this research/ study /procedures. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted in Government Yoga & Naturopathy Medical College, Chennai – 600 106

What is the Purpose of the Research?

The purpose of this study is to evaluate the effects of classical five element acupuncture versus western acupuncture in pre-exam anxiety of medical students.

The Study Design:

Comparative study with 60 students treated with five element and western acupuncture

Study Procedures:

Participants will be initially assessed for anxiety a day before the basic science university exam, followed by interventions and reassessments. Assessments include blood pressure and heart rate analysis and anxiety questionnaires.

Possible Risks to you: nil

Possible benefits to you:

Anxiety can be managed effectively through Acupuncture and balancing the energy flow can minimize the psychological and physiological burden upon you. This will further help to perform better with focus and easy retrieval of memorized topics/ answers in the exam.

Possible benefits to other people:

The result of the research may provide benefits to the society in terms of advancement of medical knowledge

Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law like the Drug Controller General of India to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

How will your decision to not participate in the study affect you?

Your decisions to not to participate in this research study will not affect your medical care or your relationship with investigator or the institution. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping the treatment

REMARKS OF THE GUIDE

This work undertaken / to be done by Dr. VIJAYAKUMAR MONICA titled "ACUTE EFFECT OF CLASSICAL FIVE ELEMENT ACUPUNCTURE AND WESTERN ACUPUNCTURE IN PRE-EXAM ANXIETY OF MEDICAL STUDENTS- A COMPARITIVE STUDY" at Government Yoga and Naturopathy Medical College Hospital, will be under my supervision and I ensure that the candidate will abide by the rules of the Institutional Ethics Committee.

Dr. R. S. Himeswari N.D (OSM)., M.Sc (Yoga)

Professor, H.O.D- Dept. of Acupuncture And Energy Medicine

Government Yoga and Naturopathy Medical College, Ch – 106

Date: